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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/562,778 | 07/27/2006 | Chai Zhonglin | 2354/370 | 7943 |

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| EXAMINER | |
|---|---|
| HADDAD, MAHER M | |

| ART UNIT | PAPER NUMBER |
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| 1644 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/562,778 | ZHONGLIN ET AL. | |
| | Examiner | Art Unit | |
| | Maher M. Haddad | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

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### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

2. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 4 and 29, drawn to a method for altering the level of an extracellular matrix (ECM) protein produced by a cell, the method including modulating expression or activity of a cell division auto antigen (CDA), wherein the cell originates for renal tissue and the agent is angiotensin II.

II. Claims 4 and 29, drawn to a method for altering the level of an extracellular matrix (ECM) protein produced by a cell, the method including modulating expression or activity of a cell division auto antigen (CDA), wherein the cell originates for vascular tissue and the agent is angiotensin II.

III. Claims 4 and 29, drawn to a method for altering the level of an extracellular matrix (ECM) protein produced by a cell, the method including modulating expression or activity of a cell division auto antigen (CDA), wherein the cell originates for renal tissue and the agent is TGFβ.

IV. Claims 4 and 29, drawn to a method for altering the level of an extracellular matrix (ECM) protein produced by a cell, the method including modulating expression or activity of a cell division auto antigen (CDA), wherein the cell originates for vascular tissue and the agent is TGFβ.

V. Claims 4 and 29, drawn to a method for altering the level of an extracellular matrix (ECM) protein produced by a cell, the method including modulating expression or activity of a cell division auto antigen (CDA), wherein the cell originates for renal tissue and the agent is connective tissue growth factor.

VI. Claims 4 and 29, drawn to a method for altering the level of an extracellular matrix (ECM) protein produced by a cell, the method including modulating expression or activity of a cell division auto antigen (CDA), wherein the cell originates for vascular tissue and the agent is connective tissue growth factor.

VII. Claims 11-16, drawn to a method for treating or preventing a condition related to synthesis of an ECM protein, the method including modulating the expression and/or activity of a CDA, wherein the condition is fibrosis.

VIII. Claims 17-18, drawn to a method for treating or preventing a condition related to synthesis of an ECM protein, the method including modulating the expression and/or activity of a CDA, wherein the condition is atherosclerosis.

IX. Claims 19-20, drawn to a method for treating or preventing a condition related to synthesis of an ECM protein, the method including modulating the expression and/or activity of a CDA, wherein the condition is aneurysm.

X. Claims 22-23, drawn to a non-human animal for use in studying disorders of the ECM, the animal having a cell capable of expressing a CDA at an altered level.

XI. Claims 24-25, drawn to a method of screening for an agent capable of modulating ECM synthesis comprising providing an animal capable of expressing a CDA.

XII. Claims 24-25, drawn to a method of screening for an agent capable of modulating ECM synthesis comprising providing a cell capable of expressing a CDA.

XIII. Claims 26-27, drawn to an agent identified by a method of screening.

XIV. Claim 28, drawn to a method for treating or preventing a condition related to an ECM protein, the method including administering to an animal in need thereof an effective amount of a pharmaceutical composition comprising an agent identified by a method of screening.

XV. Claims 31-32, drawn to a method of diagnosing a condition related to the synthesis of a ECM protein in an animal comprising obtaining a biological sample from the animal and determining the level of CDA in the sample.

Claims 1-3, 5-9 and 30 link inventions I-VI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims, claims 1-3, 5-9 and 30.

Claims 10 and 21 link inventions VII-VIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims, claims 10 and 21.

Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a

continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. The inventions listed as Groups I-XV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group III was found to have no special technical feature that defined the contribution over the prior art of Border et al (US Pat. No.7,214,375), as evidence of Ozbun et al (Genomics 73:179-193(2001) (see entire document).

Border teaches and claims a method of decreasing (altering the level) the deleterious accumulation of extracellular matrix (ECM) associated with a pathology or a condition wherein TGF-β-induced production and deleterious accumulation of extracellular matrix in a tissue exists comprising: providing an anti-TGF-β antibody that binds to TGF-β; and contacting the tissue with the anti-TGF-β antibody that binds to TGF-β ; whereby the binding of the anti-TGF-β antibody to the TGF-β suppresses the deleterious accumulation of the TGF-β-induced extracellular matrix in the tissue, and wherein the pathology or condition is glomerulonephritis. (see claim 1). While the `375 patent is silence with respect to "modulating expression or activity of a cell division auto antigen (CDA), Ozbun et al teach that DENTT (CDA) mRNA induction by TGF-β1 correlates with induction of TGF-β1 mRNA, induction of extracellular matrix gene expression, and inhibition of colony formation in soft agarose in TGF-β1 responsive NSCLC cells when expressed to TGF-β1. Moreover, TGF-β1 does not induce DENTT mRNA expression in TGF-β1 nonresponsive NSCLC cells. Ozbun reported a novel TGF-β1 target gene with distinct domains for direction to different subnuclear locations (see abstract in particular). Accordingly, TGF-β modulate expression and activity of CDA/DENTT.

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

***Species Election***

4. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

A. If Group I-VI is elected, applicant is required to elect a specific ECM protein such as the one recited in claims 2-3, a specific cell such as the one recited in claim 5. These are distinct species because their structures and modes of action are different which, in turn, address different therapeutic endpoints.

B. If Group VII is elected, applicant is required to elect a single major organ fibrosis such as the one recited in claim 14, which is due to a condition such as the one recited in claims 15 and 16). These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

5. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species,** including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B. O'Hara can be reached on (571) 272-0878. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 14, 2008

/Maher M. Haddad/
Primary Examiner,
Art Unit 1644